patients was 14%. There was no evidence of stent migration.

Conclusion: We observed strut fractures in 13.6% of the nitinol SFA stents at 18 mos. mean follow-up. Restenosis defined by arterial duplex doppler occurred in 14% of all stents and in 7% of fractured stents. Fluoroscopic and arterial duplex-doppler follow-up of the entire 78 patient cohort (105 stents) is ongoing. Presently, the clinical significance of the observed stent fractures is uncertain.

9:30 a.m.

868-5 **Long-Term Outcome of Superficial Femoral Artery Stenting Using Self-Expandable Nitinol Stents Compared to Stainless Steel Stents: A Retrospective Multicenter Study**

Bibi Fatemeh Haverizadeh, Thomas Zeller, Hans Krankenberg, Dierk Scheinert, Aljosha Rastan, Sven Bräunlich, Andrej Schmidt, Sylvio Geier, Susanne Ropers, Giancarlo Biamino, Herzzentrum Leipzig, Leipzig, Germany, Center for Cardiology, Angiology and Vascular Interventions, Hamburg, Germany

Background: With the aim to establish the long-term value of stenting long superficial femoral artery (SFA) lesions, the data of four German high-volume centers were retrospectively evaluated.

Methods: Among consecutive SFA stenting procuedures in our centers during 1999-2000, 163 SFA stenting procedures using self-expanding nitinol stent (SMART stent, Cordis; Group S) were compared with 166 implantation procuedures using self-expandable stainless steel stent (Wallstent, Boston Scientific)in the same time window (Group W). Patients with in-stent stenting and multiple stent types in the same vessel were excluded.

Results: Patients' mean age was 68.5+/-10.1 and 32% were females without statistically significant difference between the two groups. Diabetics included 21% of the S group comparing 40% in the W group (p: 0.001). Clinical symptoms based on Rutherford criteria were: (II: S: 19%, vs W: 10%, III: S:72% vs W:77%, IV: S:5% vs W:10%, V: S:3% vs W:3%; p: NS). 18% of the Smart group had previous target lesion angioplasty comparing 23% in the wallstent group (p: NS). There was no difference between the two groups comparing lesion length (S: 178+/-110 vs W: 197+/-101 mm p:NS), percent stenosis (S: 97.9+/-4.8 vs W: 97.2+/-9.9 %) and number of stents (S&W: 1.8+/-1.0). Overall stented length was longer in the wallstent group (S: 120+/-78 vs W: 143+/-98 mm, p:0.04).

Mean follow-up period was 16.9+/-8 months. Using Kaplan-Meier analaysis, one-year primary patency in the smart group was significantly higher compared to the wallstent group (S: 61+/-5% vs W: 30+/-5, p: 0.0000). One-year assisted primary patency increased to 75+/-4% in the S group and 53+/-5% in the W group (p: 0.0000). Secondary patency at one-year was 79+/-4% in the S group vs 64+/-5% in the W group (p: 0.007).

Conclusion: - Stenting long SFA lesions with nitinol stents is associated with a significantly better outcome comparing self-expandable stainless steel stents.

- The long-term secondary patency of about 80% using nitinol stents demonstrates that this technology is safe, clinically very effective and comparable with reported surgical results.

9:45 a.m.

868-6 **Renal Angioplasty and Stenting Under Distal Protection**

Michel Henry, Isabelle Henry, Christos Klonaris, Michèle Hugel, I.L.R.M.D.T., Nancy, France

Purpose: Renal artery stenting is safe & efficient but at least 20% of the patients have a deterioration of the renal function after the procedure. We evaluate feasibility and safety of renal artery angioplasty and stenting using a distal protection device to reduce the risk of intraprocedural artery embolism and to avoid deterioration of the renal function. **Methods:** 46 Hypertensive patients (28 men ; mean age 67.7 ± 8.3 years, range (22-87) with atherosclerotic renal artery stenosis (6 bilateral) underwent angioplasty & stenting with distal protection in 52 renal arteries (48 ostial lesions). 3 patients had solitary kidney, 15 renal insufficiency. The lesion was crossed either with a Guard Wire temporary occlusion balloon (n=38), which was inflated to provide parenchyma protection or with a filter (EPI Filter) (n=13), Angioguard (n=1) which allow a continuous flow. Generated debris was aspirated and analyzed, blood pressure and serum creatinine levels followed.

Results: Immediate technical success = 100 %. All lesions except 1 were stented. Visible debris was aspirated with the Percusurge or removed with filters. Mean particle number and diameter = 98.1 ± 60.0 per procedure (range 13-208) and 201.2 ± 76.0 %m (range 38-6206), respectively. Mean renal artery occlusion time = 6.55 ± 2.46 mn (range 2.29-13.21) with the Percusurge Device. Mean time in situ (filters): 4.2 ± 1.1 mn.

Mean follow-up = 23.8 ± 14 months (range 1.-42). Systolic and diastolic blood pressure declined from 169.0 ± 15.1 & 104.0 ± 13.0 mm Hg, respectively, to 149.8 ± 12.3 & 92.8 ± 6.7 mm Hg after procedure. The mean cretonne level remains constant during the follow-up. At 6 month follow up (31 patients); renal function did not deteriorate in any patient, whereas 6 patients with baseline renal insufficiency improved after the procedure. At 3 years (19 patients) renal function deteriorated only in 1 patient with renal insufficiency. The renal function remains improved in 5 patients.

Conclusion: These first results suggest the feasibility and safety of distal protection during renal interventions to protect against atheroembolism and to avoid renal function deterioration. The beneficial effects should be evaluated by randomized studies.

ORAL CONTRIBUTIONS

877 Stent Outcomes: Intravascular Ultrasound Assessment

Wednesday, April 02, 2003, 10:30 a.m.-Noon
McCormick Place, Arie Crown

10:30 a.m.

877-1 **An Optimal Diagnostic Threshold of Minimum Stent Area to Predict Long-Term Stent Patency Following Sirolimus-Eluting Stent Implantation: Serial Intravascular Ultrasound Analysis From the SIRIUS Trial**

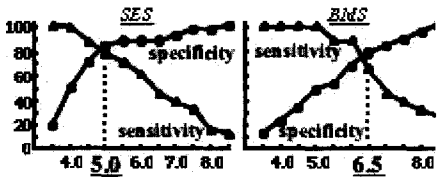
Shinjo Sonoda, Yoshihiro Morino, Junya Ako, Ali Hassan, Mark Reisman, Shing C. Wong, Theodore A. Bass, Alan C. Yeung, Martin B. Leon, Jeffrey W. Moses, Paul G. Yock, Yasuhiro Honda, Peter J. Fitzgerald, the SIRIUS Investigators, Stanford University Medical Center, Stanford, CA, Lenox Hill Hospital, New York, NY

Minimum stent area (MSA) is a consistent predictor of instent restenosis. In bare metal stents (BMS), however, its predictive value is still limited because of biologic variability in the restenosis process. The aim of this study was to examine the diagnostic value of MSA in prediction of long-term patency of drug-eluting stent (sirolimus-eluting stents, SES) implantation compared to BMS.

Methods: From the SIRIUS trial, 126 (SES 74; BMS 52) cases with complete serial IVUS (baseline and 8 months follow-up) were analysed. MSA at post-procedure and minimum lumen area (MLA) at follow-up were obtained. Based on previous physiology studies, adequate stent patency at follow-up was defined as MLA > 4.0 mm^2.

Results: In both groups, a significant positive correlation was observed between baseline MSA and follow-up MLA (SES: p<0.0001, BMS: p<0.0001). However, SES showed higher correlation than BMS (0.80 vs. 0.65) with a higher regression coefficient (0.92 vs. 0.59). The sensitivity and specificity curves identified different optimal diagnostic thresholds of MSA for adequate follow-up MLA: 5.0 mm^2 for SES and 6.5 mm^2 for BMS. The positive predictive values with these cut-off points were 90% and 56%, respectively.

Conclusions: Based on the SIRIUS IVUS substudy, in SES, MSA is a stronger predictor of outcome than in BMS, due to the reduction of biologic variability. In addition, SES has a considerably lower optimal MSA threshold (5.0 mm^2) compared to BMS (6.5 mm^2).



10:45 a.m.

877-2 **Influence of Calcium on Neointimal Growth Following Drug-Eluting and Bare Metal Stents Implantation: A 3-D Intravascular Ultrasound Substudy of the SCORE Trial**

Toru Kataoka, Yoshihiro Morino, Brian K. Courtney, Rachna Basisht, Seung-Ho Hur, Paul G. Yock, Eberhard Grube, Peter J. Fitzgerald, Yasuhiro Honda, for the SCORE Investigators, Stanford University, Stanford, CA, Heart Center Siegburg, Siegburg, Germany

Background: Plaque characteristics may affect pharmacokinetics of drug-eluting stents and, therefore, neointimal (NI) growth suppression. The aim of this study was to examine the potential influence of plaque calcium (CA) deposits on NI growth following 7-hexanoyltaxol-eluting stent (DES) and bare metal stent (BMS) implantation.

Methods: In SCORE, complete 6-month follow-up 3D IVUS data were available in 41 lesions (DES: 22, BMS: 19). Volume indices (volume/stent length) were computed for stent (SVI), lumen (LVI), and neointima (NVI). Lumen and stent contours were extracted from the dataset at 0.5 mm intervals over the stented segment. The contours were then exported into custom-designed software to compute mean NI thickness within 12 equally-spaced radial sectors in each frame, referenced from the stent center (DES: 8,040, BMS: 7,224 sectors). The presence and location of CA deposit (none: N, superficial: S, deep: D) were also evaluated at each sector.

Results: Overall, DES reduced NI growth compared to BMS (0.3±0.3 mm^3/mm vs 2.7±1.6 mm^3/mm, p<0.0001). In BMS, larger NI growth was observed at non-calcified plaque segments compared to those with superficial or deep CA. In contrast, with DES the NI growth suppression was comparable in calcified and non-calcified segments (Figure).